K072728

APR 22 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information

Establishment

Address	Siemens AG Medical Solutions Henkestrasse 127 D-91052 Erlangen Germany
Registration Number	3002808157
Contact Person	Ms. Sabine Schroedel Regulatory Affairs Manager Phone: +49-(9131) 84-8285 Fax: +49 (9131) 84-2792

Device Name

Trade Name	*syngo* MultiModality Workplace (sMMWP) (VE26A)
Classification	Picture Archiving and Communications System (PACS)
Classification Panel	Radiology
CFR Section	21 CFR §892.2050
Device Class	Class II
Product Code	LLZ

Date of Preparation of Summary: March 17, 2008

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Intended Use

The *syngo* MultiModality Workplace is intended to be used for viewing, manipulation, communication, and storage of medical images and data exchange media.

The *syngo* MultiModality Workplace can be used as a stand-alone device or as with a variety of cleared and unmodified *syngo*- and Windows XP-based software options.

The *syngo* MultiModality Workplace does not support the display of mammography images for diagnosis.

Device Description

This premarket notification covers only the Siemens *syngo* MultiModality Workplace (sMMWP) (VE26A), a *syngo*-based workplace that supports different modalities. *syngo* is a universal imaging platform based on Windows XP. *syngo* MultiModality Workplace (sMMWP) (VE26A) offers a comprehensive solution to view, optimize process diagnostic information and aid the doctors in the evaluation of digital radiological examinations and patient information.

Due to special customer requirements based in the modality image type and the clinical focus, the *syngo* MultiModality Workplace (sMMWP) (VE26A) can be offered with different combinations of cleared and unmodified clinical applications. *syngo* applications can be added to the MultiModality Workplace either individually or as clinically focused packages.

Technological Characteristics

The *syngo* MultiModality Workplace (sMMWP) (VE26A) will be marketed as a software only solution for the end user (with recommended hardware requirements) or as a complete workstation for the end user (hardware and software package). It will be installed by Siemens service engineers. The *syngo* MultiModality Workplace (sMMWP) (VE26A) described supports DICOM formatted images and information. The workplace is based on the Windows XP operating system.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.
Risk Management is ensured via a Risk Analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

Substantial Equivalence

The *syngo* MultiModality Workplace (sMMWP) (VE26A), addressed in this premarket notification, is substantially equivalent to the following commercially available device:

Predicate Device Name	*FDA Clearance Number*	*Manufacturer*
syngo MultiModality Workplace	K061964	Siemens

The *syngo* MultiModality Workplace (sMMWP) (VE26A) described in this premarket notification has the same intended use and similar technical characteristics as the device listed above.

In summary, Siemens is of the opinion that the *syngo* MultiModality Workplace (sMMWP) (VE26A) does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2008

Siemens AG, Medical Solutions
% Mr. Stefan Preiss
TUV SUD America, Inc.
1775 Old Highway 8 NW
NEW BRIGHTON MN 55112-1891

Re: K072728
Trade/Device Name: syngo MultiModality Workplace (sMMWP) (VE26A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 4, 2008
Received: April 9, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) _____
Device Name: __ ***syngo*** **MultiModality Workplace (sMMWP) (VE26A)** _____

Indications for Use:

The *syngo* MultiModality Workplace is intended to be used for viewing, manipulation, communication, and storage of medical images and data exchange media.

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Prescription Use _____X_____ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line – continue on another page if needed)

Concurrence of the CDRH of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072728